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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/750,032

12/31/2003

Timothy W. Vanderveen

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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

RAJ, RAJIV J

ART UNIT

PAPER NUMBER

3626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,032	Applicant(s) VANDERVEEN, TIMOTHY W.	
	Examiner RAJIV J. RAJ	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>31 December 2003, 14 November 2005, 12 February 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 31 December 2003.
2. Claims 1-24 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statements filed 31 December 2003, 14 November 2005, & 12 February 2007 have been considered. Initialed copies of the Form 1449 are enclosed herewith.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5. Claims 17 & 20-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent, a method/process claim must (1) be tied to another statutory class of invention (such as a particular apparatus) (see at least *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (see at least *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972)). A method/process claim that fails to meet one of the above requirements is not in compliance with the statutory requirements of 35 U.S.C. 101 for patent eligible subject matter. Here claims 17 & 20-24 fail to meet the above requirements because they are not tied to another statutory class of invention. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. See *Benson*, 409 U.S. at 71-72. As *Comiskey* recognized, "the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter." *Comiskey*, 499 F.3d at 1380 (citing *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir. 1989)). Incidental physical limitations, such as data gathering, field of use limitations, and post-solution activity are not enough to convert an abstract idea into a statutory process. In other words, nominal or token recitations of structure in a method claim do not convert an otherwise ineligible claim into an eligible one.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 1-7, 9-21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlotterbeck et al. (US 2004/0128162 A1) (hereinafter Schlotterbeck) in view of Allen, III (US 4731726) (hereinafter Allen).
9. **Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim 1

Schlotterbeck as shown discloses the following limitations:

- *the medication administration information including a plurality of medication administration parameters and a parameter value associated with each medication administration parameter; (see at least Schlotterbeck [0017])*
- *a database operatively connected to the central processor for storing medication administration guidelines representing acceptable values for the medication administration parameters; (see at least Schlotterbeck [0036])*
- *means for communicating medication administration information from each of the medication administration devices to the central processor; (see at least Schlotterbeck Fig:2 Items:110-116 & related text)*
- *wherein the central processor is further configured to compare the parameter values to the acceptable values for the parameters in the medication administration guidelines (see at least Schlotterbeck [0039])*

Schlotterbeck does not disclose the following limitations, however Allen, as shown does:

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- *a memory associated with each medication administration device for storing medication administration information associated with the medication delivered to each patient, (see at least Allen Fig:2 Items:150-154 & related text)*
- *a central processor configured to receive medication administration information from each of the medication administration devices; (see at least Allen Fig:4 Items:10, 102-106 & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Schlotterbeck. One of ordinary skill in the art would have added these features into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 2

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Allen further discloses the following limitations:

- *a central computer display operatively connected to the central processor (see at least Allen Fig:4 Items:10, 102-106 & related text)*
- *the central processor is further configured to display the medication administration information on the central computer display (see at least Allen Fig:1 Items:12 fig:2 & related text)*

It would have been obvious to one of ordinary skill in the art to add the features of Allen into Schlotterbeck. One of ordinary skill in the art would have added these features into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 3

The combination of Schlotterbeck/Allen disclose all the limitations of claim 2. Schlotterbeck further discloses the following limitation:

- *the central processor is further configured to provide a visual indication on the central computer display if one of the parameter values does not fall within the acceptable values for the parameter in the corresponding medication administration guideline (see at least Schlotterbeck [0067])*

Claim 4

The combination of Schlotterbeck/Allen disclose all the limitations of claim 2. Schlotterbeck further discloses the following limitation:

- *the central computer display is located in a pharmacy (see at least Schlotterbeck Fig:1 Items:32,36 & related text)*

Claim 5

The combination of Schlotterbeck/Allen disclose all the limitations of claim 3. Allen further discloses the following limitations:

- *means for a clinician to adjust the medication administration parameter values in response to the visual indication (see at least Allen Column:6 Lines:45-50)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 6

The combination of Schlotterbeck/Allen disclose all the limitations of claim 5. Allen further discloses the following limitations:

- *means for the clinician to report to a caregiver at the point of care the adjusted medication administration parameter values (see at least Allen Column:2 Lines:40-47)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting

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administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 7

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Schlotterbeck further discloses the following limitation:

- *the central processor is further configured to automatically adjust the medication administration parameter values in response to an indication that one of the parameter values does not fall within the acceptable values for the parameter in the corresponding medication administration guideline (see at least Schlotterbeck Claim:9)*

Claim 9

The combination of Schlotterbeck/Allen disclose all the limitations of claim 2. Schlotterbeck further discloses the following limitation:

- *means for communication between a caregiver located at one of the medication administration devices and a clinician located at the central computer display (see at least Schlotterbeck Fig:2 Items:100,112,114 & related text)*

Claim 10

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Schlotterbeck further discloses the following limitation:

- *the medication administration parameters include current medication administration device operating parameters (see at least Schlotterbeck [0044])*

Claim 11

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Schlotterbeck further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on patient condition data (see at least Schlotterbeck [0036])*

Claim 12

The combination of Schlotterbeck/Allen disclose all the limitations of claim 11. Schlotterbeck further discloses the following limitations:

- *a memory operatively connected to the central processor for storing patient condition data associated with each patient; (see at least Schlotterbeck [0037] & [0038])*
- *wherein the processor is further configured to compare the parameter values to the acceptable values for the parameters in the medication administration guidelines corresponding to the stored patient condition data associated with each patient (see at least Schlotterbeck Claim:1)*

Claim 13

The combination of Schlotterbeck/Allen disclose all the limitations of claim 12. Schlotterbeck further discloses the following limitation:

- *the patient condition data for each patient includes current physiological status (see at least Schlotterbeck [0044])*

Claim 14

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Schlotterbeck further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on medication indication data (see at least Schlotterbeck [0036])*

Claim 15

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Schlotterbeck further discloses the following limitations:

- *a memory in which is stored medication order information for a plurality of patients, the medication order information including a plurality of prescribed medication administration parameters for delivering medication to each patient and a parameter value associated with each prescribed medication administration parameter; (see at least Schlotterbeck [0017])*

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- *wherein the processor is further configured to compare the parameter values of the prescribed medication administration parameters to the acceptable values for the medication administration parameters in the medication administration guideline (see at least Schlotterbeck [0039])*

Claim 16

The combination of Schlotterbeck/Allen disclose all the limitations of claim 15. Allen further discloses the following limitation:

- *a central computer display operatively connected to the central processor and wherein the central processor is further configured to display the medication order information and the medication administration information on the central computer display (see at least Allen Fig:1 Items:12,14, Fig:2 & related text)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 17

Schlotterbeck as shown discloses the following limitations:

- *the medication administration information including a plurality of medication administration parameters and a parameter value associated with each medication administration parameter; (see at least Schlotterbeck [0036])*
- *storing a database of medication administration guidelines representing acceptable values for the medication administration parameters; (see at least Schlotterbeck [0036])*
- *communicating the medication administration information and the medication administration guidelines to a central location; (see at least Schlotterbeck Fig:2 Items:110-116 & related text)*

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- *comparing the parameter values to the acceptable values for the parameters in the medication administration guidelines; (see at least Schlotterbeck [0039])*
- *providing an indication at the central location if one of the parameter values does not fall within the acceptable values for the parameter in the corresponding medication administration guideline (see at least Schlotterbeck [0067])*

Schlotterbeck does not disclose the following limitations, however Allen, as shown does:

- *monitoring medication administration information associated with medication delivered to each patient (see at least Allen Claim:1)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 18

The combination of Schlotterbeck/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *displaying the medication administration information on a computer display at the central location (see at least Allen Fig:1 Items:12 fig:2 & related text)*

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 19

The combination of Schlotterbeck/Allen disclose all the limitations of claim 18. Schlotterbeck further discloses the following limitation:

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- *providing an indication at the central location includes displaying an alert on the computer display* (see at least Schlotterbeck [0067])

Claim 20

The combination of Schlotterbeck/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *adjusting the medication administration parameter values from the central location in response to the indication* (see at least Allen Column:6 Lines:45-50)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 21

The combination of Schlotterbeck/Allen disclose all the limitations of claim 17. Allen further discloses the following limitation:

- *communicating information from the central location to a care-giver located at the point of care* (see at least Allen Column:2 Lines:40-47)

It would have been obvious to one of ordinary skill in the art to add the feature of Allen into Schlotterbeck. One of ordinary skill in the art would have added this feature into Schlotterbeck with the motivation of providing an improved method and system for monitoring and adjusting administration of medication for more effective patient healthcare. (see at least Allen Column:1 Lines:62-68 Column:2 Lines:1-15)

Claim 23

The combination of Schlotterbeck/Allen disclose all the limitations of claim 17. Schlotterbeck further discloses the following limitation:

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- *the medication administration guidelines include the acceptable values for the medication administration parameters based on patient condition data (see at least Schlotterbeck [0036])*

Claim 24

The combination of Schlotterbeck/Allen disclose all the limitations of claim 17. Schlotterbeck further discloses the following limitation:

- *the medication administration guidelines include the acceptable values for the medication administration parameters based on medication indication data (see at least Schlotterbeck [0036])*

10. Claims 8 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlotterbeck in view of Allen in further view of Kaufman et al. (US 5267174) (hereinafter Kaufman).

Claim 8

The combination of Schlotterbeck/Allen disclose all the limitations of claim 1. Kaufman further discloses the following limitation:

- *the central processor periodically compares the parameter values to the acceptable values for the parameters in the medication administration guidelines throughout the administration of the medication (see at least Kaufman Column:19 Lines:12-16)*

It would have been obvious to one of ordinary skill in the art to add the feature of Kaufman into Schlotterbeck/Allen. One of ordinary skill in the art would have added this feature into Schlotterbeck/Allen with the motivation to provide an adjustable and a more effective interactive medication delivery device. (see at least Kaufman Column:2 Lines:15-28)

Claim 22

The combination of Schlotterbeck/Allen disclose all the limitations of claim 17. Kaufman further discloses the following limitation:

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- *periodically comparing the parameter values to the acceptable values for the parameters in the medication administration guidelines throughout the administration* (see at least Kaufman Column:19 Lines:12-16)

It would have been obvious to one of ordinary skill in the art to add the feature of Kaufman into Schlotterbeck/Allen. One of ordinary skill in the art would have added this feature into Schlotterbeck/Allen with the motivation to provide an adjustable and a more effective interactive medication delivery device. (see at least Kaufman Column:2 Lines:15-28)

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **571-270-3930**. The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Luke Gilligan** can be reached at **571.272.6770**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> <<http://pair-direct.uspto.gov>>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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Date: 07/08/08

/Rajiv J Raj/ Patent Examiner Art Unit 3626

/Robert Morgan/

Primary Examiner, Art Unit 3626